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HEALTH RESEARCH GOVERNANCE: ARGENTINE STAKEHOLDER OBJECTIVES

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Policy Brief 5:2010

Drawing on empirical research conducted in Argentina through the ESRC-funded 'GET: Social Values Project' (see <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/>), this Policy Brief (1) offers a very brief overview of the biotechnology research setting in Argentina, (2) provides evidence of stakeholder views on the need for research regulation in the regenerative medicine setting, (3) provides evidence of stakeholder views on the desired content for research regulation in the regenerative medicine setting, and (4) offers some general recommendations for policy in this field.

BIOTECHNOLOGY IN ARGENTINA

Despite suffering from many of the conditions which hinder innovation and population health in developing countries (ie: fragmented and under-funded healthcare systems, insufficient regulatory guidance, inadequate translational support), Argentina has signalled its intent in the biosciences field by:

1. adopting the Buenos Aires Declaration, which explicitly enumerates biotechnology as a key developmental objective;
2. forming the federal Ministry of Science, Technology and Productive Innovation, which has undertaken a variety of initiatives to stimulate research excellence, including the formation of the Advisory Commission on Regenerative Medicine and Cellular Therapies;
3. making public research funds available so that it might better compete,¹ and
4. promoting international networks and signing international agreements with specified groups to encourage scientific innovation and international cooperation.²

"As a consequence of the interest of the Minister of Science, I think this [stem cell research] is one of the things that is growing fast in the country. Now we have, besides these ten projects, this cluster for stem cell research that involves nine different institutions in the country with fourteen different projects."

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1. The Argentine government remains the primary funding source for science, with the majority of research being performed in governmental institutions and universities: Ministerio de Ciencia y Tecnología de la República Argentina, Indicadores Ciencia Y Tecnología: Argentina 2006, available at The Argentine government remains the primary funding source for science, with the majority of research being performed in governmental institutions and universities: Ministerio de Ciencia y Tecnología de la República Argentina, Indicadores Ciencia Y Tecnología: Argentina 2006, available at http://www.mincyt.gov.ar/indicadores_2006/publicacion/indicadores_2006.pdf [accessed 13 January 2010]. [accessed 13 January 2010].
2. J. Niosi and S. Reid, "Biotechnology and Nanotechnology: Science-Based Enabling Technologies as Windows of Opportunity for LCDs" (2007) 35 World Development 426-438, N. Bar, "El Rating de la Ciencia", *La Nación*, 13 May 2009, available at http://rcdtx.lanacion.com.ar/nota.asp?nota_id=1127536 [accessed 3 August 2009].

Indeed, Argentina has already established itself in the agro-biotech industry,¹ the animal research setting,⁴ and various support industries,⁵ and it has a long history of excellence in health-related research.⁶ Now, it appears to be targeting health biotechnology, and in particular stem cell research, as an arena in which to build comparative advantages. For example, it is undertaking cutting edge research at the FLENI Institute, Hospital Garrahan, Leloir Institute, and others, and is engaged in the related field of bioinformatics, focusing on the use of information technologies in healthcare management.⁷ This is a very general history and current research context with which most of the respondents in the GET: Social Values Project were familiar.

NEED FOR REGULATION

Most respondents felt that internationally-informed standards for good science combined with rational boundaries and some oversight would be ideal for, and is needed in, Argentina. For example, respondents stated as follows:

I think that today, you need to regulate because the power and the possibilities ... and the possible effects are so terrible that today, with a lot of care ... and consulting specialists and [bioethicists], something must be done. You can't leave scientists to do what they want. The risks are too much.

I think they need to regulate scientific practice. But very, very rational regulation. The problem is that sometimes regulation is based on emotional questions and not really rational questions. But I think the people who are working [in] law need to be bold. I think we need a leash between science and law. People with both information.

In particular, it was felt that clear regulations are needed for the transition of work from basic research to the clinical setting:

We are far from the clinic. ... I think that the translation from basic to clinic has to be a very regulated, exquisite regulated process. There's a lot of safety measures, peer review process, to be extremely well looked at.

Yes, yes. I think all the basic and clinical research in human beings have to be regulated by the Ministry of Science. I understand the general research is one [but] you have different stages that [need regulation].

However, frustration was expressed at the perceived unlikelihood of achieving

"The law has to intervene on some scientific contexts. . The law provides limits which cannot be provided by biology."

"Science is moved by cost/effect . and law moves on the social effect. Science describes the world of being and the law the world of what must be."

³ It is the fourth largest producer of GM crops: see E. Trigo and E. Cap, "Ten Years of Genetically Modified Crops in Argentine Agriculture", 2006, available at http://www.inta.gov.ar/ies/docs/otrosdoc/resyabst/ten_years.htm [accessed 4 August 2009], and W. Surman, "GM Crops in Argentina" (2007) *New Agriculturalist*, available at <http://www.new-ag.info/07/02/develop/dev2.php> [accessed 4 August 2009].

⁴ D. Salamone et al., "High Level Expression of Bioactive Recombinant Human Growth Hormone in the Milk of a Cloned Transgenic Cow" (2006) 124 *J Biotechnology* 469-472.

⁵ It manufactures materials for biofertilisers and is using bioplastics in the production of milk bottles: E. DaSilva, "Review: Biotechnology: Developing Countries and Globalization" (1998) 14 *World J Microbiology & Biotechnology* 463-486, at 481-482.

⁶ P. Kreimer and M. Lugones, "Rowing Against the Tide: Emergence and Consolidation of Molecular Biology in Argentina, 1960-90" (2002) 7 *Science, Technology and Society* 285-311.

⁷ E. DaSilva, note 5 above, at 483.

rational regulation in this setting, or of informed people (particularly scientists) actively shaping that regulation. Respondents opined as follows:

Yes, [we need a law] but [a] rational [law]. I am afraid because in the past when the government [adopts] legislation about science—well not really good. ...

It is very difficult to pass a logical law in [reproductive medicine] ... which is a related field. ... It is not only the Church, but also a lot of newspapers that are very controlling in the way they [present] abortion and [similar] topics.

To be honest, I am so sceptical of the possibility of regulating stem cell research that I totally understand why some people would much rather say, 'let's not start anything'.

Nonetheless, most respondents concluded that, regardless of the governmental course, scientists must form their own views about boundaries, should engage and network with other interested parties (eg: academics, bioethicists, etc.), and should encourage and take part in public discussions.

CONTENT OF REGULATION

On the issue of the content research (including clinical research) regulation, respondents in the GET: Social Values Project identified issues such as:

1. clear and strict professional standards;
2. training needs for IRBs;
3. identification of values to guide research ;
4. articulation of broad objectives for research;
5. protections for research subjects and patients,
6. oversight of research activities; and
7. sanctions for unprofessional behaviour and breach of prohibitions.

It was felt that known boundaries would have at least two salutary effects. First, they would limit scientists by making clear what ends and/or methods are deemed to be (in)appropriate after existing methods and trajectories had been considered rationally (ie: it would reduce the possibilities of mavericks damaging the science/research reputation and agenda).⁸ Second, they would empower scientists in a positive way by assuring them that all of their activities within that articulated sphere are defensible and need not be sheltered from public scrutiny (ie: it would encourage the unveiling of science without putting scientists on the defensive).

However, although almost all respondents felt that *government* boundary-setting would be valuable, there was no consensus on how that boundary-setting might be achieved, and they did not all agree that formal regulation was essential. In this regard, opinions fell broadly into four camps:

- Camp 1 – No Legislation: It is too early for legislation in the stem cell setting (R7). Alternatively, legislation ought to be avoided because the

"I think you have [to have] clear cut ideas or regulatory assistance, with a clear framework of what has to be done in this area: what type of cells you are going to work with; what area of methodology; or whatever. And this is a double ethical need because there are public funds."

⁸ Returning to the social/science environment and the cell metaphor, unchecked science can easily go out of control and/or lose social utility, and might be seen as cancer.

tendency in Argentina is to ban and pass bad laws (R16). It might be better for this area to first be overseen by a regulatory committee under the Ministry of Science or Health so some oversight and advice can be offered as the field develops, and any furore is avoided (R21).

- Camp 2 – Specific Legislation: A stem cell-specific law is important because of the socially important issues thrown up by this research (R5, R10, R11, R14, R17, R19).
- Camp 3 – General Research Legislation: Stem cell practices and issues are shared with other research and medical practices and techniques so a general medical research law is more useful, under which technique-specific regulations might be drafted by the executive on an as-needed basis (R1, R4, R6, R8, R18).
- Camp 4 – General Medical Legislation: It is much more important to regulate the clinical setting than basic research; the safety of the patient is the most important element currently missing from the Argentine biomedical regulatory setting so it would be better to have a medical law (R3, R12, R15).

In short, there was a plurality of opinions as to how the bioscience environment should respond and shape itself with respect to science boundary-setting, and there was a scepticism as to whether it could shake itself into action and set a course that engaged with this plurality (and other pluralities that might arise).

RECOMMENDATIONS FOR ARGENTINA

Given the plurality of opinions on how to proceed, the evidence generated by the GET: Social Values Project does not offer any firm basis for choosing a regulatory path. However, it makes several key issues very clear, namely that most respondents:

- desire rational boundary-setting for science in some form;
- desire a regulatory framework that incorporates core values, including the value of knowledge and the freedom to work and the protection of individuals;
- see a need for improved ethics education (within science) and science education (in the community);
- desire improved spaces to network and discuss (and ultimately influence) policy debates relating to science trajectories and boundaries.

Ultimately, the relationship (and particular power dynamic) between certain central actors (eg: the church, media and political elites) was viewed as creating a bottleneck, blocking other actors from a more active role within the social/science environment. It was felt that this needs to be addressed if the rational regulation that is desired is to become a reality.

"I think the elements [of good governance] would be to provide the good regulation. to communicate well, to stimulate research. to put initiatives [on the subject] on debate and get the subject to the public before it is a reality."



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For more on the GET: Social Values project, visit <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/>